

REMARKS

Claims 1-2, and 4-15 are currently pending in the application. Applicants have canceled claim 3, added claim 15, and amended claims 1, 4, 12, and 14. Applicants request reconsideration of the application in light of the following remarks.

Rejections under 35 U.S.C. §102

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1-2 and 7-14 were rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by Parks (U.S. Patent No. 4,685,901, hereinafter “Parks”). Applicants respectfully traverse this rejection and request reconsideration of the claims.

Claim 3 has been canceled and the matter thereof has been incorporated into independent claim 1. Claim 3 was previously rejected under U.S.C. § 103, but the matter thereof as combined with claim 1 is now considered to be allowable for the reasons set forth below.

Claim 1 has been amended to include the specifics of original claim 3, and now recites that “a distal end of the inner tube is in a range from approximately 2 cm to approximately 4 cm from a distal end of the outer tube”. This detail is not provided by Parks. Therefore, rejection under USC 102 is no longer proper.

Furthermore, separating the distal ends of the inner and outer tubes from each other in this range provides a great advantage in jejunal feeding and aspirating that is not taught by Parks. Therefore, the relative positioning of the distal ends in this range is not merely a matter of design

choice, and a rejection under U.S.C. § 103 based on Parks is not proper. It would not have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the separation of the distal ends of the inner and outer tubes in the range from approximately 2 cm to approximately 4 cm as claimed because doing so provides a specific advantage not contemplated or met by Parks, and Parks' device does not and cannot function to provide the same advantage as that of the present invention without modification. The only teaching to modify Parks' device to meet current claim 1 is Applicant's own disclosure. The **MPEP section 2144.04 VI. (C)** on patentability based on design choice states that: "The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device."

The advantage that the tube assembly of the present invention achieves is the advantage of feeding into the jejunum and suctioning from the jejunum generally simultaneously. Locating the aspirating tube in the jejunum together with the feeding tube as does the claimed invention is contrary to the teachings of Parks. It appears that Parks has a goal of separating the distal end 56 of the aspirating tube from the distal end 51A of the feeding tube by a large distance in order to prevent liquid feedings from being removed. (See column 2, lines 14-18, and Figure 6 of Parks.) In fact, Parks' device takes advantage of natural valves between organs to restrict the possibility of the food from being aspirated by the aspirating tube so that if a patient has trouble with gastric reflux, the feedings in the jejunum will remain while liquid may be removed from the stomach. That is, the natural valves between the stomach and the duodenum and generally between the duodenum and the jejunum lie between the distal ends 51A and 56 of the feeding and aspirating tubes of Parks. These natural valves are formed by the **pylorus** and the **Ligament of Treitz**, respectively, and they form one way valves that generally inhibit flow in the upstream direction of the digestive tract. Thus, the aspirating tube 56 can be used to remove liquid from the stomach without removing feedings to the jejunum with the Parks device. Conversely, Applicant's goal is to

place the aspirating tube within a close range of the distal end of the feeding tube and within the same organ (jejunum) in order to facilitate removal of excess feedings. As disclosed in the present application, Applicant's device has a goal of reducing build up of too much food by aspirating any excess and refeeding it as the patient's system is able. Otherwise, the build up of excess feedings may cause discomfort, distension of the intestinal tract, injury, and possible death of the patient. Applicant accomplishes removal of excess feedings by placing the distal end of the feeding tube only slightly downstream of the distal end of the aspirating tube within the range claimed. This configuration has the advantage of moving the feedings forward slightly while exploiting the natural valves that tend to hold the feedings in a more localized position within the jejunum where they are readily accessible by the distal end of the aspirating tube so that removing excess feedings is facilitated.

Additionally, Claim 1 also recites that "the second inner feeding tube is removably disposed inside the first outer aspirating tube". The removably disposed aspect appears to have been lightly passed over in the previous Office action. However, Parks does not appear to disclose that the inner tube 51 is removably disposed within the outer tube. Therefore, claim 1 is considered to further define over Parks.

Furthermore, providing the removable inner tube in jejunal feeding and aspirating systems is not trivial. Rather, in the present invention, removal of the inner tube permits feeding of courser more viscous feedings through the larger diameter outer tube once the inner tube has been removed. Feeding of courser, more viscous foods can advantageously include feeding natural foods that are more nutritious and far less expensive. Using the full cross section of the inner diameter of the outer tube advantageously permits a higher delivery rate into the intestines and has less propensity for clogging so that delivery of more viscous feedings is possible. This is an advantage once the patient's digestive tract is capable of absorbing such feedings without aspiration, for example.

Claims 2 and 7-11 are considered to be allowable as depending from an allowable base

claim and for additional details therein as may be appreciated by the Examiner.

Claim 12 has been amended to include recitation that specifically points out and distinctly claims that the distal or internal ends of each of the feeding and aspirating tubes are placed in the jejunum. This is different from what Parks' device does, as set forth in the arguments for allowance of claim 1 above. Therefore, it is requested that the rejection of claim 12 under USC 102 be withdrawn.

Parks' device is for a different purpose as shown in the Figures of Parks. Parks' disclosure does not show or teach the method of claim 12. In particular, Parks does not disclose the additional step of aspirating from the jejunum through the outer tube, as does the present invention. As set forth above, aspirating from the jejunum as claimed in claim 12 is contrary to the goal of Parks of leaving the feedings in the jejunum and aspirating only from the stomach. Still further, the method of claim 12 achieves a great advantage not achieved or contemplated by Parks, as set forth in the arguments for claim 1 above, and rejection based on obviousness of design choice requires a teaching from the prior art to make the changes that are considered part of the design choice. Thus, claim 12 cannot properly be rejected under USC 103 in view of Parks, and allowance thereof is respectfully requested.

Claims 13 and 14 are considered to be allowable as depending from an allowable base claim and for additional details therein as may be appreciated by the Examiner.

Therefore, withdrawal of the rejections of claims 1-2, 7-11, and 13-14 and allowance thereof are earnestly requested.

Rejections under 35 U.S.C. §103

To establish a *prima facie* case of obviousness under 35 U.S.C. §103, three basic criteria

must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the cited prior art reference must teach or suggest all of the claim limitations. Furthermore, the suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based upon the Applicants' disclosure. A failure to meet any one of these criteria is a failure to establish a *prima facie* case of obviousness. MPEP §2143.

Claims

Claim 1 has been amended to include the matter of claim 3, which was rejected under 35 U.S. C. § 103(a) previously. However, amended claim 1 is considered to overcome the rejections under both 35 U.S. C. § 102(b) and 35 U.S. C. § 103(a) as set forth in the arguments for allowance of claim 1 above.

Claims 3-6 were rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Parks (U.S. Patent No. 4,685,901). Applicants respectfully traverse this rejection and request reconsideration of the claims.

Claim 3 has been canceled and the matter thereof has been incorporated into independent claim 1. Therefore, the rejection of claim 3 has been obviated.

Claims 4-6 recite greater detail than does the matter of currently amended claim 1, which has been argued as patentable over Parks above. Thus, claims 4-6 are non-obvious in view of Parks similarly to claim 1. As such, claims 4-6 are considered to be allowable as depending from an allowable base claim 1 and for the additional details therein as may be appreciated by the Examiner. Claim 4 has been further amended to correct its dependency and one other non-substantive error. Therefore, Applicant respectfully requests withdrawal of the obviousness rejections of claims 4-6 and allowance thereof.

New Claim

New claim 15 has been added to seek rightful coverage of matter deemed to be different from that shown and disclosed in the prior art. Specifically, claim 15 now recites: "A tube assembly for jejunal feeding and jejunal aspirating". Parks clearly does not provide jejunal aspirating as has been argued above. Claim 15 further recites: "a first outer jejunal aspirating tube; and a second inner jejunal feeding tube". At least one of the tubes 56 of Parks is not a jejunal tube, but is to be placed in the stomach as a gastric tube. In fact, providing both feeding and aspirating tubes as jejunal tubes as recited in claim 15 is contrary to the teachings of Parks as discussed above. Furthermore, there is no advantage or motivation for modifying the device of Parks to have the distal ends positioned so as to both be within the jejunum.

Claim 15 also recites that "the second inner jejunal feeding tube is removably disposed inside the first outer jejunal aspirating tube". The removably disposed aspect appears to have been lightly passed over in the previous Office action. However, important advantages are achieved by providing the feature in the present invention. Parks does not disclose that the inner tube 51 is removably disposed within the outer tube. Therefore, claim 15 is considered to further define over the art previously relied upon.

Therefore, claim 15 is considered to be allowable and notice of the same is respectfully requested.

Regarding Doctrine of Equivalents

Applicants hereby declare that any amendments herein that are not specifically made for the purpose of patentability are made for other purposes, such as clarification, and that no such changes shall be construed as limiting the scope of the claims or the application of the Doctrine of Equivalents.

CONCLUSION

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any fees, including extension of time fees or additional claims fees, are due as a result of this response, please charge Deposit Account No. 19-0513. This authorization is intended to act as a constructive petition for an extension of time, should an extension of time be needed as a result of this response. The examiner is invited to telephone the undersigned if this would in any way advance the prosecution of this case.

Respectfully submitted,

Date:

By



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